## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE SEP 2 3 2003 CEATER TRONSON **DIAMANDIS** Examiner: O. CHERNYSHEV 10/036,308 Group Art Unit: 1646 11757.58USU1 Filed: OCTOBER 26, 2001 Docket: 23552 Confirmation No.: 2749 Customer No.: METHODS FOR DETECTING ALZHEIMERS DISEASE Title: **CERTIFICATE UNDER 37 CFR 1.8:** I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, with sufficient postage, in an envelope addressed to: Commissioner for Patents, P.O., Box 1450, Alexandria, VA 22313-1450 on September 15, 2003.

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

We are transmitting herewith the attached:

☑ Transmittal Sheet in duplicate containing Certificate of Mailing
 ☑ Information Disclosure Statement, Form 1449, 15 References
 ☑ Check in the amount of \$180.00 for information disclosure statement fee

Return postcard

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers or any future reply, if appropriate. Please charge any additional fees or credit overpayment to Deposit Account No. 13-2725. A duplicate of this sheet is enclosed.

MERCHANT & GOULD P.C. P.O. Box 2903, Minneapolis, MN 55402-0903 612.332.5300

Name: Mark T. Skoog Reg. No.: 40,178 MSkoog:sab

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

**DIAMANDIS** 

Examiner:

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O. CHERNYSHEV 2900

Serial No.:

10/036,308

Group Art Unit:

1646

Filed:

OCTOBER 26, 2001

Docket No.:

11757.58USU1

Confirmation No.:

2749

Customer No.:

23552

Title:

METHODS FOR DETECTING ALZHEIMERS DISEASE

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**CERTIFICATE UNDER 37 CFR 1.8:** 

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on September 15, 2003.

Name: Sheryl A. Boorboom

## **INFORMATION DISCLOSURE STATEMENT (37 C.F.R. § 1.97(c))**

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

With regard to the above-identified application, the items of information listed on the enclosed Form 1449 are brought to the attention of the Examiner.

This statement should be considered because it is submitted after the mailing date of a first Office Action on-the-merits or a first Office Action after filing a Request for Continued Examination under 37 C.F.R. § 1.114 or a CPA under 37 C.F.R. § 1.53(d), but before the mailing date of: i) a final action under 37 C.F.R. § 1.113; ii) a Notice of Allowance under 37 C.F.R. § 1.311; or iii) an action that otherwise closes prosecution on the application. Enclosed is a check in the amount of \$180.00 under 37 C.F.R. § 1.17(p) for consideration of the items listed on the enclosed Form 1449.

In accordance with 37 C.F.R. §1.98(a)(2), a copy of each document or other information listed on the enclosed Form 1449 is provided.

No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102 and 103 and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish that the reference(s) are not "prior art." Moreover, Applicants do not represent that a

reference has been thoroughly reviewed or that any relevance of any portion of a reference is intended.

Consideration of the items listed is respectfully requested. Pursuant to the provisions of M.P.E.P. 609, it is requested that the Examiner return a copy of the attached Form 1449, marked as being considered and initialed by the Examiner, to the undersigned with the next official communication.

Please charge any additional fees or credit any overpayment to Deposit Account No. 13-2725.

Respectfully submitted,

MERCHANT & GOULD P.C. P.O. Box 2903 Minneapolis, MN 55402-0903 (612) 332.5300

Dated: Sept 15, 2003

Mark T. Skoog Reg. No. 40,178

FORM 1449* INFORMATION DISCLOSURE STATEMENT	Docket Number: 11757.58USU1	Application Number: 10/036,308
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EXAMINER INITIAL	DOCUM	IENT NO.	DATE	NAME	CLASS	SUBCLASS		G DATE OPRIATE
	5,733,768		03/31/1998	DIXON ET AL.				
			FOR	EIGN PATENT DOCU	MENTS			
	DOCUMENT NO.		O. DATE COUNTRY	CLASS	SUBCLASS	TRANSLATION		
							YES	NO
	1092767 A	A1	04/18/2001	ЕР				
	0576152 E	31	06/11/2002	ЕР				
	9-149790		06/10/1997	JP				X
	WO 98/11	238	03/19/1998	PCT				
		OTHER	DOCUMENTS	(Including Author, Title,	Date, Pertinent I	Pages, Etc.)		
		Diamandis, E. et al., "Human Kallikrein 6 (Zyme/Protease M/Neurosin): A New Serum Biomarker of Ovarian Carcinoma", <u>Clinical Biochemistry</u> , 33(7):579-583 (2000)  Hoffman, BR et al., "Immunofluorometric quantitation and histochemical localization of kallikrein 6 protein in ovarian cancer tissue: a new independent unfavorable prognostic biomarker", British Journal of Cancer, 87:763-						
		<ul> <li>T71 (2002)</li> <li>Little, S. et al., "Zyme, a Novel and Potentially Amyloidogenic Enzyme cDNA Isolated from Alzheimer's Disease Brain", The Journal of Biological Chemistry, 272(40) 25135-25142 (1997)</li> <li>Mitsui, S. et al., "Decreased Cerebrospinal Fluid Levels of Neurosin (KLK6), an Aging-Related Protease, as a</li> </ul>						
		Possible New Risk Factor for Alzheimer's Disease", Ann. N.Y. Acad. Sci., 977:216-223 (2002)						
		Ogawa, K. et al., "Localization of a novel type trypsin-like serine protease, neurosin, in brain tissues of Alzheimer's disease and Parkinson's disease", <u>Psychiatry and Clinical Neurosciences</u> , 54:419-426 (2000)						
		Petraki, C. et al., "The Spectrum of Human Kallikrein 6 (Zyme/Protease M/Neurosin) Expression in Human Tissues as Assessed by Immunohistochemistry", <u>The Journal of Histochemistry &amp; Cytochemistry</u> , 49(11):1431-1441 (2001)						
		Yamanaka, H. et al., "Protease M/neurosin mRNA is expressed in mature oligodendrocytes", Molecular Brain Research, 71:217-224 (1999)						
		Yamashiro, K. et al., "Molecular cloning of a novel trypsin-like serine protease (neurosin) preferentially expressed in brain", Biochimica et Biophysica Acta, 1350:11-14 (1997)						
				lar Characterization of Zy ease", Genomics, 62(2):2:		eurosin (PRSS9), A	A Hormonall	y Regulate

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EXAMINER	DATE CONSIDERED	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.

FORM 1449*  OVP EINFORMATION DISCLOSURE STATEMENT	Docket Number: 11757.58USUI	Application Number:
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Zarghooni, M. et al., "Decreased concentration of human kallikrein 6 in brain extracts of Alzheimer's disease patients", Clinical Biochemistry, 35:225-231 (2002)

**EXAMINER** 

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.